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10/785,158	02/23/2004	Martin C. Hinz	3364.25US-01	8497

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EXAMINER
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KOLKER, DANIEL E

ART UNIT	PAPER NUMBER
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1649

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01/31/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/785,158

Applicant(s)

HINZ, MARTIN C.

Examiner

Daniel Kolker

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11, 16-18, 21, 28-32, 46-50, 54, 55, 57-59, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 11, 16-18, 21, 28-32 and 46-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-55, 57-59, 61-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. The remarks and amendments filed 13 November 2007 have been entered. Claims 11, 16 - 18, 21, 28 - 32, 46 - 50, 54 - 55, 57 - 59, and 61 - 62 are pending.

#### ***Election/Restrictions***

2. Claims 11, 16 - 18, 21, 28 - 32, and 46 - 50 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2 May 2006.
3. Claims 54 - 55, 57 - 59, and 61 - 62 are under examination.

#### ***Withdrawn Rejections and Objections***

4. The following rejections and objections set forth in the previous office action are withdrawn:
  - A. The rejection of claims 56 and 60 under 35 USC 112, first paragraph is moot as the claims are canceled.
  - B. The rejection of claims 56 and 60 under 35 USC 112, second paragraph is moot as the claims are canceled.
  - C. The rejection under 35 USC 102(b) over Ross is withdrawn in light of the amendments. Ross does not explicitly teach assaying body fluids and determining both serotonin and catecholamine levels and administering precursors of both systems as recited in independent claims 54 and 59.
  - D. The rejection under 35 USC 102(b) over Siirtola is withdrawn in light of the amendments. Siirtola does not explicitly teach assaying body fluids and determining both serotonin and catecholamine levels and administering precursors of both systems as recited in independent claims 54 and 59.

#### ***Rejections Maintained and Necessitated by Amendment***

##### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54 and 57 – 58 are rejected under 35 U.S.C. 102(b) as being anticipated by 1A Technology 2(10):15 October 2001, as evidenced by 1A Technology 3(1):15 January 2002.

This rejection stands for the reasons previously made of record. Briefly, 1A Technology newsletter, dated 15 October 2001, teaches administration of medication including those called "1A Extra" (p. 1, column 2 steps 2 – 4). While the 15 October 2001 newsletter does not detail the ingredients of "1A Extra", the company's newsletter from 15 January 2002 teaches two formulations of "1A Extra". The old formula (presumably that on sale before January 2002) had both tyrosine and 5-HTP; the new formula had both ingredients as well as folic acid. See 15 January 2002 newsletter, p. 1 columns 1 – 2. Thus the 15 January 2002 newsletter provides evidence that "1A Extra", described in the October 2001 newsletter, contains both 5-HTP (a serotonin precursor as recited in claim 57) and tyrosine (a catecholamine precursor as recited in claim 58). Clearly, 1A Technology taught administration of both precursors "substantially simultaneously" as recited in claim 54 part(a).

1A Extra (October 2001) also teaches assaying body fluids to determine both serotonin and norepinephrine levels (note norepinephrine is a catecholamine); see p. 1 column 2 step 4. This is on point to claim 54, part(b). The reference also teaches administering repeated doses of the precursors (see p. 1 final paragraph which teaches administration of "1A cysteine plus" to increase norepinephrine levels and p. 2 first paragraph which teaches administration of additional 5-HTP if serotonin level is low). While "1A cysteine plus" is not explicitly listed as containing catecholamine precursors, it is reasonable that such precursors are there, given that the instructions in both the 15 October 2001 (p. 1 final paragraph) and 15 January 2002 (p. 2 second column 3<sup>rd</sup> paragraph) indicate that "1A Cysteine Plus" is to be given to patients with low catecholamine levels. Thus the 1A October 2001 reference teaches every step of claim 54 part(c). The reference also teaches repeated administration and testing as recited in claim 54 part(d); see 1A October 2001 p. 1 final paragraph and p. 2 first column.

The examiner notes that the two 1A Technology newsletters do not explicitly state that the process is to be repeated until "small increases in dosage of the first monoamine amino acid neurotransmitter precursor results in a large increase in the serotonin neurotransmitter levels and small increases in dosage of the second monoamine amino acid neurotransmitter precursor results in a large increase in the catecholamine neurotransmitter levels" as recited in claim 54

part(d). However, such a level is in fact achieved. Note that 1A Technology October 2001 teaches that the proper range of serotonin for appetite suppression is 1200 to 2400 (no units given; p. 2 first sentence); this is the therapeutic range defined by applicant on p. 17 line 17 – 18 of the specification. 1A Technology October 2001 also teaches that norepinephrine should be 40 to 80 (no units given; p. 1 final paragraph), which specifically names points within the range considered by applicant to be therapeutic (specification, p. 18 lines 6 - 7). Thus, the final limitation of the claim is necessarily met.

6. Claims 54 – 55, 57 – 59 and 61 – 62 are rejected under 35 U.S.C. 102(b) as being anticipated by 1A Technology 3(1):15 January 2002.

1A Technology January 2002 teaches administration of "1A Extra", which contains 5-HTP and tyrosine. The reference also teaches that prior to administration, a neurotransmitter test should be performed to measure the levels of serotonin and catecholamines (p. 1 column 2 and p. 2 column 1). The reference is thus on point to claim 54 part (a), as well as claim 55 (drawn to performing the test prior to administration of precursors) and claim 59 parts (a) and (b). The reference also is on point to claims 57 and 61 as it teaches 5-HTP, and claims 58 and 62 as it teaches tyrosine.

1A Technology January 2002 teaches assaying body fluids after the administration of precursors, to determine serotonin and catecholamine levels (p. 2 column 1 final paragraph and column 2 first paragraph), which is on point to claim 54 part (b) and claim 59 part (c). The reference also teaches repeated administration and testing; see p. 1 column 2 which indicates escalating doses of 1A Extra are to be given as well as p. 2 which indicates that repeated testing should be done to follow patient progress. Thus the reference is on point to claim 54 part (c) and claim 59 part (d). While the reference does not explicitly teach administration so that certain changes are observed as recited in claim 54 part(d) and claim 59 part(c), the reference clearly teaches that therapeutic ranges for catecholamines and serotonin are to be achieved (p. 2 columns 1 – 2), as required by the claim. The additional recitation of the "wherein" clause of these claims describes what would happen if additional doses were given, but does not require such to be administered. Note that no actual level of any neurotransmitter is recited in the claim; the claim only requires that the range be "therapeutic". As 1A Technology January 2002 teaches every element of the claims, the reference anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54 – 55, 57 - 59, and 61 – 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siirtola (1975. Clin Neurol Neurosurg 78(2):77 – 88) in view of Ross (1999. The Diet Cure, of record).

This rejection stands for the reasons previously made of record. The reasons why Siirtola is on point to the specific limitations recited in the claims are set forth in the previous office action and for the sake of brevity will not be repeated. Briefly, Siirtola teaches methods comprising measurement of the neurotransmitter dopamine in subjects' urine samples and administration of the dopamine amino acid precursor L-dopa (also called levodopa). The reference teaches measuring both dopamine and 5-HIAA, the main metabolite of serotonin. Claims 54 and 59 do not explicitly require measurement of serotonin; the claims recite "assaying a body fluid of the subject to determine a serotonin neurotransmitter level". Since 5-HIAA is indicative of 5-HT (serotonin) levels, the reference by Siirtola is on point to claim 54 part (b) and claim 59 part(c). Siirtola teaches administration of L-dopa increases dopamine and decreases 5-HIAA. L-dopa is a catecholamine precursor and therefore is on point to claims 54 and 59, and is recited in claims 58 and 62. As set forth previously, the reference teaches repeated administration as required by the claims. However Siirtola does not teach administration of a precursor of serotonin as required by claims 54 and 59.

Ross teaches that when serotonin (5-HT) levels are low, one effective way to boost serotonin levels is to consume 5-HTP. Specifically, at p. 123 second paragraph Ross teaches the artisan of ordinary skill "... another supplement you can take to boost serotonin is 5-HTP". The reference is therefore on point to claim 54 part (a) and 59 part(b), as well as claims 57 and 61 which encompass administration of 5-HTP. Ross also discusses other amino acid precursors which could be used to increase dopamine levels (see p. 120), however Ross does not explicitly teach administration of L-dopa as recited in claims 58 and 62.

It would have been obvious to one of ordinary skill in the art to modify the method of Siirtola to administer both L-dopa and 5-HTP, with a reasonable expectation of success. The motivation to do so comes directly from the prior art references. Siirtola teaches assaying both dopamine and 5-HIAA, which are indicative of levels of dopamine and serotonin respectively, and teaches that administration of L-dopa increases dopamine but decreases the amount of serotonin. This provides the motivation to the skilled artisan to look for ways to boost serotonin, to compensate for this side effect of L-dopa administration. The reference by Ross directs the artisan of ordinary skill to administer 5-HTP to boost serotonin levels, thereby guiding selection of both L-dopa and 5-HTP as the neurotransmitter precursors to be administered, and arriving at the invention set forth in claims 54 – 55, 57 – 59 and 61 – 62.

Applicant argues on p. 13 of the remarks that recitation of the final clause of independent claims 54 and 59 distinguishes them from the prior art references. The examiner disagrees. The clause after “wherein” defines certain characteristics of the therapeutic range. The claims do not require that any particular range of neurotransmitter levels be achieved, and do not require that the small increases in dosage of each precursor are steps which are actually carried out. Since the references by Siirtola and Ross give guidance as to therapeutic ranges generally, which is all that is required by the claims, they are on point to the claims as written. Applicant also argues that “monoamine amino acid neurotransmitter include only one amino group and include the substances histamine glutamine serotonin, norepinephrine, dopamine, and epinephrine.” While this is true, these particular limitations are not recited in any claim. Furthermore, the list of these neurotransmitters is not particularly on point, as the claims allow for many precursors to be given (see claims 57 - 58 for example) and allow for several neurotransmitters to be studied.

#### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54 – 55, 57 – 59, and 61 – 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "substantially simultaneously", "small increases", and "large increase" in claims 54 and 59 are relative terms which render the claim indefinite. The terms "substantially simultaneously", "small increases", and "large increase" are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 55, 57 – 58, and 61 – 62 are rejected as they depend from a rejected base claim but do not clarify this ambiguity.

### ***Double Patenting***

9. Claims 54 – 55, 57 – 59, and 61 – 62 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 29 of copending Application No. 11/282965. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the '965 case would anticipate the claims in the instant case. The claims in the '965 case set forth additional steps beyond those explicitly recited in the instant claims; however use of the open claim language "comprising" is inclusive of features and limitations beyond those recited in the claims. Thus the claims in the '965 case would anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant acknowledged but did not traverse the rejection. Applicant indicated a terminal disclaimer may be filed in the future, however none has yet been received. The rejection stands for the reasons of record.

### ***Conclusion***

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Daniel E. Kolker, Ph.D.  
January 28, 2008



ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER